

**Office of Surveillance and Epidemiology (OSE)/ Office of Pharmacovigilance and
Epidemiology (OPE)
Divisions of Pharmacovigilance (I and II)
Goals and Objectives for Pharmacy Student Rotations**

I. Goals:

- A. To familiarize the student with the role of CDER, OSE, and DPV I-II in post-marketing safety.
- B. To assist DPV I-II in our mission to protect public health by detecting and analyzing postmarketing adverse event data to identify drug safety concerns and recommend actions to improve product safety.

II. Learning Objectives. Upon completion of this rotation, the student will be able to:

- A. Explain the FDA's mission, functions, and organizational structure, including the role of DPV I-II within the FDA.
- B. Discuss laws, regulations, and guidance documents related to post-marketing drug safety.
- C. Discuss basic principles of Pharmacoepidemiology and Pharmacovigilance.
- D. Describe the origin of postmarketing reports in Adverse Event Reporting System (AERS) Database.
- E. Explain the roles and responsibilities of a post-marketing safety evaluator in DPV I-II within the FDA.
- F. Utilize available resources to identify and evaluate potential safety signals (e.g. AERS, data mining, scientific literature, etc).
- G. Explain post-marketing surveillance mechanisms that OSE uses to identify drug safety concerns and recommend actions to improve product safety.
- H. Demonstrate acceptable qualities and characteristics of professional behavior in areas of confidentiality, communication, appearance, timeliness, commitment, and initiative.

III. Student Requirements (may include, but not limited to)

- A. Given a preceptor-approved topic, provide a written summary and an oral presentation describing a postmarketing safety issue.
- B. Complete ancillary preceptor-approved assignments (e.g. journal club; drug safety-related, regulatory/policy-related, or therapeutics-related topic discussions).
- C. Participate in training and meetings as assigned by the preceptor.

IV. Student Assessment and Grading: The preceptor will assess the student on performance and professionalism at the midpoint and end of the rotation.